Remarks

This Amendment is in response to the Office Action dated **October 28, 2010.** Claims 1, 2, 4-14, 35-38 and 55-57 are pending in this application. The Office Action rejected all of the pending claims under 35 USC § 103 over Bashiri (US 2003/0045923) in view of Acosta (US 7137993) and further in view of Killion (US 5938697).

By this amendment, claims 4, 6 and 36 are amended. The amendments to claims 4 and 6 are supported at least by Figure 5 and page 10, lines 15-22. The amendment to claim 36 is supported at least by Figure 9 and page 11, lines 24-25. The rejections asserted in the Office Action are traversed. Reconsideration in view of the above amendments and following remarks is requested.

Claim Rejections – Independent Claim 2

An obviousness rejection requires a suggestion of all limitations in a claim. See *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Claim 2 recites "wherein at least a portion of said at least one disengagable connector strut is made from a material having a higher corrosion potential than a material used to form said serpentine bands." This recitation, contrary to the assertion of the Office Action, is not suggested by the applied references.

The Office Action asserts that Acosta teaches the above limitations, providing the following reasoning in the Office Action at pages 3-4:

> Acosta teaches coupling an electrical lead to the disengagable struts to induce electrolytic detachment of the struts having reduced thickness portions (for example, see Figure 7) and inherently higher corrosion potential than the rest of the device (otherwise the entire device would corrode simultaneously destroying the device), wherein corrosion reduces the mass of the metal framework (see column 6, lines 18-40 for details).

Acosta does not provide any explicit teaching that the "reduced thickness portions" of Acosta have a higher corrosion potential. Acosta does not discuss corrosion

potential. With respect to chemical detachment, Acosta provides a chemical agent that chemically degrades the link. Thus, the Office Action relies on an inherency theory.

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

The inherency argument presented in the rejection is flawed because it does not provide a reasonable basis to support the assertion that the Acosta frangible elements must have a higher corrosion potential than the remainder of the stent.

Figure 7 of Acosta, referenced in the Office Action, shows a beam with a weakened segment. The Office Action reasons that the "disengagable struts" of Acosta must inherently have a higher corrosion potential than the rest of the device otherwise the entire device would "corrode simultaneously destroying the device." This reasoning is not sound because even if the entire device were to corrode simultaneously, there is no evidence that the device would be destroyed. To the contrary, one would expect the "disengageable strut" to break first, because of the thinned area. In short, the remainder of the device would not be destroyed.

Therefore, the rejection has not established a suggestion of each limitation in claim 2, and has not presented a *prima facie* case of obviousness against claim 2. Applicants request withdrawal of the rejection asserted against claim 2.

Please note that claim 57, which depends upon independent claim 35, also includes the "corrosion potential" limitation. Applicants request withdrawal of the rejection asserted against claim 57.

Claim Rejections – Independent Claims 1 and 35

The rejection under 35 USC § 103 proposes two modifications to the Bashiri stent – one modification in view of Killion and one modification in view of Acosta. In view of Killion, the rejection proposes to add connector struts to the Bashiri stent. In view of Acosta, the rejection proposes to substitute electrolytic detachment for the mechanical frangibility taught by Bashiri. See Office Action at page 4.

The Office Action fails to present a *prima facie* case of obviousness because the

rejection is not supported by clear and particular reasoning that would have prompted a person of ordinary skill in the art to make the proposed modifications.

No Reason to Modify Connector Struts (Killion Modification)

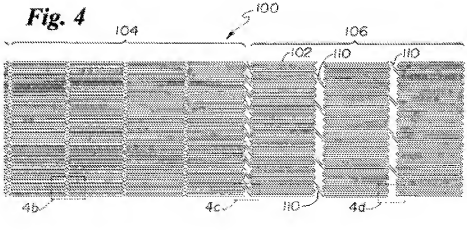
Independent claim 1 recites, "the first serpentine band connected to the second serpentine band by at least one permanent connector…each remaining valley of the first serpentine band connected to a peak of the second serpentine band by a disengagable connector strut."

Independent claim 35 similarly recites, "each permanent connector strut connecting a valley of the first serpentine band to a peak of the second serpentine band, the plurality of disengagable connector struts connecting the remaining valleys of the first serpentine band to the remaining peaks of the second serpentine band."

The Office Action admits that the Bashiri stent does not have connector struts connecting between all of the adjacent peaks and valleys, and proposes to add connector struts "such that all of the peaks and valleys of each adjacent band are connected by a connector (permanent or disengagable)." See Office Action at page 4. This assertion is traversed.

The Examiner's proposal to add connector struts (e.g. elongate connectors) to Bashiri is not supported by the teachings of Killion.

Killion discloses that a portion of the Killion stent (the "closed cell" portion indentified in the Office Action) has *direct connections* between the serpentine bands, wherein the peaks of one band are *directly connected* to the valleys of the adjacent band (see Figure 4 of Killion, below, specifically length segment 104 and the *direct connections* in box 4b).



The open-cell portion of the Killion stent, on the other hand, uses serpentine bands that are spaced apart and uses actual connector struts 110 that span the gap between the bands – see e.g. length portion 106 in Figure 4, above. It should be noted that the open-cell portion does not provide a connector strut 110 for each peak/valley.

As noted by the Examiner, Killion does teach that the closed cell portion (directly connected serpentine bands) provides more strength, whereas the open cell portion provides more flexibility. See e.g. column 3, lines 24-30. However, Killion's teachings regarding closed and open cell configurations would not have motivated a person of ordinary skill in the art to add connector struts to Bashiri.

Modification for Strength

It should be noted that the meaning of "closed cell" as used by Killion is different from the meaning of "closed cell" as previously used by Applicants in this application,[1] and that proposing to modify Bashiri to be "closed cell" in view of Killion would not result in a stent that meets the limitations of the rejected claims. If, for the sake of argument only, one of ordinary skill in the art had the motivation to make the proposed combination of Bashiri and Killion in order to strengthen the stent, the resulting structure would include a region having *direct connections* between peaks and valleys of adjacent serpentine bands of the Bashiri stent. That structure, however, would lack *connecting struts* between each of the peaks and valleys of a first and second serpentine bands, and would not meet the limitations of the rejected claims.

Modification for Flexibility

If a modification were desired to increase flexibility of Bashiri, there would be no reason to add connector struts. Thus, the modifications to Bashiri that would actually be motivated by the teachings of Killion would not result in a stent that meets the limitations of the rejected claims.

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1 The Amendment filed August 30, 2010, stated "A person of ordinary skill in the art would recognize that claim 1 requires a "closed-cell" stent design, wherein a connector spans between each peak/valley of the adjacent serpentine bands." See page 5.

Reasoning Asserted in Rejection

To support the proposed modification to add connector struts, regardless of whether the connector struts are permanent or disengagable, the Office Action asserts the following reasoning at page 4:

> Doing so would provide the stent with an initial high radial strength, in which the disengagable connector struts may be selectively disengaged to impart the desired flexibility for the intended application.

This statement does not provide a reason that would have motivated a person of ordinary skill in the art to modify Bashiri as proposed in the rejection. The rejection appears to assert that if the Bashiri stent had more connector struts, it would have a higher level of radial strength; however, a person of ordinary skill in the art would recognize that adding connector struts will not necessarily make the stent more resistant to radial compression. A person of ordinary skill in the art would recognize that radial strength in the Bashiri stent generally stems from the serpentine band structures, as it is the serpentine bands that deform and change shape when the stent expands and/or contracts. The individual connector struts merely form a bridge between adjacent serpentine bands and do not comprise any structure that can resist radial compression in and of itself – any resistance to radial compression exhibited by a connector strut stems from its attachment to the serpentine bands. For example, Killion states "Greater or fewer connectors actually are used to vary the flexibility along the length of the stent more than increasing radial force."

Thus, the modification proposed in the rejection will not impart radial strength to the Bashiri stent.

The rejection's statement that "disengagable connector struts may be selectively disengaged to impart the desired flexibility for the intended application" is not supported by the applied references. The Examiner has not cited to a reference that discusses any "selective disengagement"[2] of frangible/disengagable connectors. The Examiner has not cited to a reference that discusses adjusting the flexibility of a stent by disengaging frangible connectors. The

2 Applicants interpret "selective disengagement" as selecting particular frangible connectors to disengage while leaving other frangible connectors attached to achieve some particular result.

"intended application" is also unclear – in Bashiri, the frangible connectors are broken upon expansion. The Examiner has not cited to any "alternative applications" for the Bashiri stent wherein different flexibilities would be desired and achieved by selective disengagement of certain frangible connectors.

The rejection further suffers from an ambiguity stemming from the proposal to add disengageble connectors for strength purposes. Since the disengageble connectors are intended to be disengaged prior to permanent implantation of the stent, the disengageble connectors do not contribute to strength over the life of the stent subsequent to implantation in a body vessel. Examiner's proposal to add connectors to each peak and valley of Bashiri, regardless of whether the connectors are permanent or disengageble, is evidence that the rejection stems from an impermissible hindsight attempt to reach the pending claims, and not any clear and particular reason to modify the prior art, as required to support a rejection under 35 USC § 103.

Therefore, the rejection has not identified a reason that would have prompted a person of ordinary skill in the art to modify the applied references as proposed in the rejection, and has not presented a *prima facie* case of obviousness against the pending claims.

No Reasonable Expectation of Success (Acosta Modification)

The Office Action proposes to modify Bashiri to substitute electrolytically detachable connectors for Bashiri's mechanically frangible connectors, stating at page 4:

> The substitution of known elements (electrical leads for providing electrolytic detachment and detachment connectors of higher corrosion potential as disclosed by Acosta) for another (a means for exerting a mechanical force and breakable detachment connectors as disclosed by Bashiri) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the detachment means would have yielded predictable results

Although the rejection characterizes the proposed modification as a simple substitution, the teachings of Acosta are so minimal with respect to electrolytic detachment that the rejection fails to present a reasonable expectation of success in achieving electrolytic

detachment in the arrangement of frangible connectors taught in Bashiri and supplemented by the modification proposed in view of Killion.

Acosta teaches a stent delivery system capable of delivering and severing multiple stents that are arranged in a particular configuration. The individual stents 122 are aligned in series within the catheter and are joined by frangible elements. A stent 122 is advanced out of the catheter and the frangible element severed by a combination of shearing elements 136, 132, which shear the frangible element via mechanical force. See e.g. Figure 9B below, and column 14, lines 49-56. The same shearing elements are used to sever the frangible elements between the remaining stents 122 in the same manner. Thus, Acosta teaches an arrangement where a shearing element located at the distal end of the stent is used multiple times to sever multiple similar frangible elements.

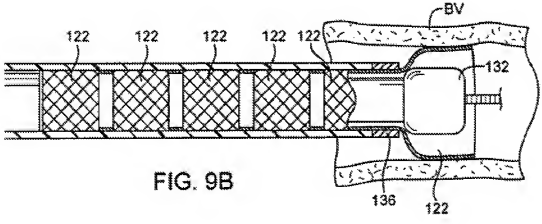


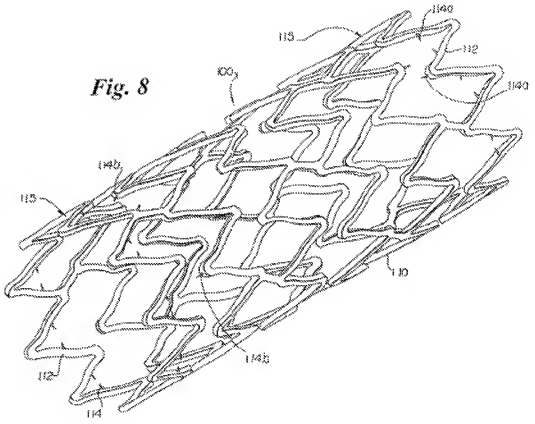
FIG. 9B

With respect to electrolytic detachment, Acosta teaches, "The shearing mechanism will usually be mechanical, but could also be electrolytic, ultrasonic, or chemical....In other cases, the shearing mechanism could be an electrode for inducing electrolytic breakage of the link, an ultrasonic transducer for mechanically degrading a susceptible link (i.e. a link having a resonant frequency which corresponds to the ultrasonic transducer), a luminal port for releasing a chemical agent selected to chemically degrade the link, or the like" (emphasis added). See column 6, lines 18-40.

The teachings in the paragraph above appear to include all of the teachings Acosta presents with respect to electrolytic detachment. Thus, the above paragraph represents all of the teachings in the record regarding electrolytic detachment.

The rejection does not explain specifically how the electrolytic detachment would be achieved in Bashiri. Acosta uses frangible links oriented in a particular way between individual stents. The rejection does not discuss how the Acosta frangible links would be implemented into the Bashiri stent, for example in the connections between struts 112 within a serpentine band (e.g. the frangible connections in Bashiri that are most effective in preventing stent expansion). The Bashiri frangible links are not large connections between individual stents as shown in Acosta Figure 9B, above, but very small connections between adjacent struts of a serpentine band. See e.g. Bashiri Figure 8, below.

Fig. 8



The modification in view of Killion proposes to add connector struts between the Bashiri serpentine bands, some of which may be frangible. The rejection does not explain how the proposed electrolytic detachment would achieve disengagement of all of the frangible connections of the modified Bashiri stent. Acosta does not teach a system of electrolytic detachment that would disengage all of the Bashiri frangible connectors.

Applicants teach that an electrical lead can split into a plurality of branches and attach to multiple disengagable connectors. Applicants further teach that a plurality of electrical leads can be used. See e.g. Figure 5 and page 10, lines 15-22. The cited references do not teach a way to achieve disengagement of all of the disengagable connections using electrolytic disengagement, or corrosion, in the way of the claimed stent, as proposed in the rejection.

Therefore, a person of ordinary skill in the art would not have a reasonable expectation of success in achieving disengagement of all of the disengagable connectors in the modified Bashiri stent proposed in the rejection, and a *prima facie* case of obviousness has not been presented.

Conclusion

Based on at least the foregoing remarks, Applicants respectfully submit that the Office Action has not presented a *prime facie* case of unpatentability of the pending claims. Favorable consideration and prompt allowance of claims 1, 2, 4-14, 35-38 and 55-57 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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